

**REMARKS**

This paper is submitted in response to the Office Communication mailed January 31, 2005. Claims 1-12 are presently pending in this application and have been subject to restriction. The Examiner alleges that the claims are drawn to 3 patentably distinct inventions as follows:

Group I: claims 1-10, drawn to a drug composition comprising microparticles from blood;

Group II: claim 11, drawn to a process for promoting regeneration of bone tissues;

Group III: claim 12, drawn to a method of using aqueous suspension of blood derived microparticles for making a drug composition;

Applicants respectfully traverse the restriction requirement. Applicants note that the full set of claims, as amended by the Preliminary Amendment dated July 17, 2003 was not considered. Applicants request that the Examiner consider the full set of claims as set forth in the Preliminary Amendment.

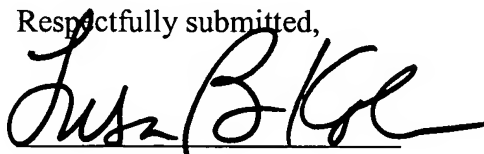
The requirement for restriction is respectfully traversed. However, in order to be fully responsive to the requirement for restriction, Applicants elect, with traverse, the claimed methods of Group I. Withdrawal of the requirement for restriction and favorable consideration and allowance is earnestly solicited.

Applicants respectfully request that amendments set forth in the Preliminary Amendment filed on July 17, 2003 be made of record. A copy of the Preliminary Amendment and of the return receipt postcard, acknowledging receipt at the United States Patent and Trademark Office is enclosed herewith.

If any additional fee is due, or if any overpayment has been made, in connection with the filing of this response, the Commissioner is authorized to charge any such fee or credit any overpayment, to our Deposit Account No. 02-4377. A duplicate copy of this paper is enclosed.

Respectfully submitted,

By:

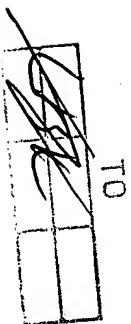
A handwritten signature in black ink, appearing to read "Lisa B. Kole", written over a horizontal line.

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BAKERBUTTS L.L.P.

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File Number: A35931-PCT-USA-A 071986.0249

The stamp of the Patent Office Mail Room hereon acknowledges receipt on the date indicated by such stamp of patent application papers comprising 10 page(s) of specification, 2 page(s) of claims, 1 page(s) of abstract, 2 sheet(s) of drawings, an unsigned Declaration by applicant(s) Watzek et al., and a Preliminary Amendment for an invention entitled  
**DRUG COMPOSITION FOR THE PROMOTION OF TISSUE REGENERATION**

Express Label No.: EV342493622US

Mailing Date: July 17, 2003

**MAIL STOP PATENT APPLICATION**

21909 U.S. PRO  
10/621894  
07/17/03

**Docketed**

For 10/17/2003 by



A35931-PCT-USA-A - 071986.0249

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Watzek et al.

Serial No. : to be assigned

Examiner: to be assigned

Filed : herewith

Group Art Unit: to be assigned

For : DRUG COMPOSITION FOR THE PROMOTION OF  
TISSUE REGENERATION

PRELIMINARY AMENDMENT

**EXPRESS MAIL NO. EV342493622US**

Commissioner for Patents  
Box 1450  
Alexandria, VA 22313-1450

Sir:

Prior to the examination of the above-identified patent application, which is filed as a continuation of International Patent Application No. PCT/AT02/00018, please make the following amendments and remarks of record.

AMENDMENTS

IN THE SPECIFICATION

Please amend the specification as follows:

Please insert, at page 1 between the title at line 1 and the first paragraph beginning on line 2, the heading:

-- This application is a continuation of International Patent Application No. PCT/AT02/00018, filed January 17, 2002, published in German on July 25, 2002 as Publication No. WO 02/056897, which is based on Austrian Patent Application No. A 89/2001, filed January 18, 2001, all incorporated by reference in their entireties.

INTRODUCTION --.

Please insert, at page 1 between the first and second paragraphs (lines 3 and 4), the heading:

-- BACKGROUND OF THE INVENTION --.

Please insert, at page 4, between lines 18 and 19 and between the sentence ending "NEJM 1994)." and "The objective. . .", the heading:

-- SUMMARY OF THE INVENTION --.

Please amend page 4 line 27 as follows:

-- Preferred embodiments of the invention ~~are defined in the attached claims~~ include (i) drug compositions that contain one or more of the following: soluble or insoluble substances promoting wound healing; cytokines and/or growth factors; a substance which constitutes or may form a provisional extracellular matrix such as for example an organic polymer such as a polyacton; collagen; fibrinogen and thrombin for the formation of a fibrin scaffold; and/or inorganic compounds, (ii) drug products comprising a drug composition as set forth above and a biocompatible material, for example titanium or an apatite; (iii) a process for promoting the regeneration of tissue, in particular the regeneration of bone tissue, characterized in that a drug

composition as set forth above is applied together with a biocompatible material such as for example titanium or an apatite; and (iv) the use of an aqueous suspension which contains virus-inactivated microparticles from blood cells and/or tissues for the preparation of a drug composition for accelerating cell growth, in particular the growth of osteoblasts.

#### BRIEF DESCRIPTION OF THE FIGURES

Figure 1 illustrates a dose-dependent proliferation of osteoblasts.

Figure 2 illustrates a dose-dependent cellular proliferation of fibroblasts.

Figure 3 illustrates a dose-dependent cellular proliferation of chondrocytes.

Figure 4 illustrates a stimulation of the differentiation of osteoblastic cells.

#### DETAILED DESCRIPTION OF THE INVENTION - -

**IN THE CLAIMS:**

Please amend the claims as follows:

Please replace "Claims" with WE CLAIM:

1. (amended) A drug composition to be applied topically for promoting the regeneration of tissue, ~~characterized in that it contains~~ comprising microparticles from blood cells and/or tissues which have been purified by a process selected from the group consisting of differential centrifugation, filtration ~~or~~ and affinity chromatography, ~~it wherein the drug composition has~~ been subjected to a procedure ~~for~~ selected from the group consisting of virus inactivation and ~~or~~ virus depletion, ~~it has been prepared under sterile conditions, and it is provided in a state~~ selected from the group consisting of a freeze-dried state and a ~~or~~ deep-frozen state.
2. (amended) A drug composition according to claim 1, ~~characterized in that it contains~~ comprising soluble or insoluble substances promoting wound healing.
3. (amended) A drug composition according to claim 1 ~~or claim 2, characterized in that it~~ contains comprising cytokines and/or growth factors.
4. (amended) A drug composition according to claim 1 ~~any of claims 1 to 3, characterized in that it contains comprising~~ a substance which constitutes or may form a provisional extracellular matrix.
5. (amended) A drug composition according to claim 1 ~~any of claims 1 to 4, characterized in that it contains comprising~~ collagen.
6. (amended) A drug composition according to claim 1 ~~any of claims 1 to 5, characterized in that it contains comprising~~ fibrinogen and thrombin for the formation of a fibrin scaffold.

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7. (amended) A drug composition according to claim 4, ~~characterized in that~~ wherein an organic polymer ~~, in particular a polylacton~~ is used as the provisional extracellular matrix.
8. (amended) A drug composition according to claim 1 ~~any of claims 1 to 7~~, characterized in ~~that it contains~~ comprising inorganic compounds.
9. (amended) A drug product ~~characterized in that it exhibits~~ comprising  
- a drug composition according to any of claims 1 to 8 and  
a biocompatible material which is applied together with the drug composition.
10. (amended) A drug product according to claim 9, ~~characterized in that~~ wherein the biocompatible material is selected from the group consisting of titanium or and an apatite.
11. (amended) A process for promoting the regeneration of tissue, ~~in particular the regeneration of bone tissue, characterized in that~~ wherein a drug composition according to any of claims 1 to 8 is applied together with a biocompatible material ~~in particular titanium or an apatite~~.
12. (amended) ~~The use of an aqueous suspension which contains virus-inactivated microparticles from blood cells and/or tissues for the preparation of a drug composition~~ A method for accelerating cell growth, in particular the growth of osteoclasts comprising administering, to a cell, an aqueous suspension comprising virus-inactivated microparticles from a source selected from the group consisting of blood cells, tissues, and a combination thereof.
13. (new) The drug composition of claim 7, wherein the organic polymer is a polylacton.
14. (new) The process of claim 11, wherein the tissue in which regeneration is promoted is bone tissue.



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15. (new)     The process of claim 11, wherein the biocompatible material is selected from the group consisting of titanium and an apatite.

16. (new)     The process of claim 12, in which cell growth is accelerated in osteoclasts.

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**REMARKS**

Claims 1-16 are pending. The specification and claims are amended and new claims are added to put the application in conformance with United States patent practice. None of the amendments or new claims constitute new matter. In particular, the amendments to page 4, between lines 18 and 19 are supported by the original claims and by the specification at page 9 lines 12, 15-18 and 22-25 and page 10 lines 12-14.

Please take this amendment into consideration before calculating the filing fee.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Lisa B. Kole', written over a horizontal line.

Lisa B. Kole

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